

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

In re Bair Hugger Forced Air Warming
Products Liability Litigation

MDL No. 15-2666 (JNE/FLN)

This Document Relates To:
All Actions

**MEMORANDUM IN SUPPORT OF
3M COMPANY’S MOTION
TO REMOVE “CONFIDENTIAL”
DESIGNATION FROM
DOCUMENTS PRODUCED BY
RIDGEVIEW MEDICAL CENTER**

(FILED UNDER SEAL)

INTRODUCTION

Defendant 3M Company requests that this Court order the removal of the “Confidential” designation from documents recently produced by Ridgeview Medical Center (“Ridgeview”), so that 3M may correct false and misleading public statements made by Dr. Scott Augustine and Plaintiffs’ counsel concerning the hospital’s purported reduction in infection rates when it switched from the 3M™ Bair Hugger™ patient warming system to Augustine’s HotDog system. These documents prove that the public statements made by Augustine and Plaintiffs’ counsel regarding Ridgeview’s infection rates are incomplete and untrue.¹ Moreover, the information contained in these documents has already been made the subject of a newspaper article, YouTube videos, papers submitted by Augustine for publication, and a litigation guide aimed at recruiting potential plaintiffs and attorneys to file lawsuits against 3M.

¹ The documents that are the subject of 3M’s motion are described in the addendum attached to the Declaration of Benjamin W. Hulse (“Hulse Decl.”) as Exhibit A.

Given the way in which this information has already been publicized by Augustine and Plaintiffs' counsel, the Ridgeview documents do not qualify for confidential treatment under the Protective Order or Rule 26(c) of the Federal Rules of Civil Procedure. Indeed, to the extent the documents could otherwise be considered confidential, such confidentiality was waived by Ridgeview when it (1) cooperated with Augustine in issuing public statements regarding their relationship and Ridgeview's infection rates, and (2) did not previously seek to prevent the public dissemination of such information by Augustine and others. It also would be contrary to the public interest to prohibit 3M from correcting the false and damaging impressions that Augustine has worked to create. Accordingly, 3M requests that the "confidential" designation be lifted and that 3M be permitted to use the Ridgeview documents for any business or legal purpose it deems appropriate.²

ARGUMENT

I. Augustine Has Used Ridgeview Information to Publicly Create the False Impression that the Bair Hugger System Increases Infection Risk.

Plaintiffs' claims in this litigation can be traced directly back to Augustine. Since 2007, Augustine has engaged in an aggressive and unorthodox effort to drive sales of his own device by improperly attempting to undermine the Bair Hugger patient warming system. Augustine falsely claims that the use of forced-air warming may increase airborne

² In response to 3M's meet-and-confer efforts, Ridgeview has agreed to de-designate a handful of the documents it produced, which represent communications between the *Star Tribune* and Ridgeview representatives. Ridgeview's agreement to remove the "confidential" classification from these documents is appropriate, considering that the information contained therein was shared with the press, but it is not enough. The remaining documents contain information that has been equally publicized and, as set forth further herein, should be treated accordingly.

contamination in operating rooms, and that this contamination presents an increased risk of infection. These allegations are knowingly deceptive and driven by a personal and competitive agenda.

Through discovery, 3M has received documents confirming that this litigation was the brainchild of Augustine all along. In an email to two of the attorneys representing Plaintiffs in this matter, Augustine's counsel wrote:

Scott and I are preparing a detailed guide to suing 3M/Bair Hugger for orthopedic implant infections. It will contain background, summaries of and links to scientific articles, explanations of joint infections, a timeline of 3M's knowledge and failure to warn, discovery suggestions. . . and a half-dozen other useful things.

We intend to offer it to other plaintiffs' firms around the country who express an interest in jumping on this bandwagon. Our staff is preparing a list of the email addresses of AAJ members who do this work, and we may do an email blast. Communications in the AAJ publications may also be a good idea.

Email from J. Randall Benham to David Hodges, Gabriel Assaad, and Scott Augustine, Apr. 25, 2013 (ellipsis in original, emphasis added) (Ex. B to Hulse Decl.).

As part of this litigation "guide," Augustine and his attorney referred to various studies that Plaintiffs now rely on in support of their allegation that the Bair Hugger system causes surgical site infections. In addition, they claim that "similar infection reduction results" were documented at Ridgeview Medical Center: "Surgeons there found that after discontinuing the use of [forced-air warming] their deep joint infection rate fell by 81% (1.55% → 0.29%), 1,065 patients, 3 years. The 0.29% deep joint infection rate was achieved while using air-free conductive fabric warming." Kennedy Hodges L.L.P., *Bair*

Hugger Warming and Peri-Prosthetic Infections in Joint Replacement Surgery: A Guide to Product Liability Litigation, at 28 (Ex. C to Hulse Decl.). According to the litigation guide, the basis for this assertion is found in “personal communication regarding information obtained from Robert Barnett MD, Orthopedic Surgeon, Ridgeview Medical Center, Waconia, MN.” *See id.*

The Ridgeview data has also been referenced as “anecdotal evidence” in publicly available YouTube videos uploaded by “HDPatient Warming” (Dr. Augustine’s HotDog patient warming system). *See* Airborne Contamination in the Operating Room, <https://www.youtube.com/watch?v=31jz3P3eH DU> at 7:02-7:47 (uploaded February 24, 2011) (“Ridgeview Medical Center, near Minneapolis, the Number 1 ranked hospital for overall patient care in Minnesota, switched from forced-air to air-free conductive fabric warming three years ago. . . . After abandoning forced air, their infection rate dropped to 0.29 percent for the last two years combined, an 81% reduction.”) and <https://www.youtube.com/watch?v=BKF12rINa9g> (uploaded May 16, 2011) (same).

The Ridgeview documents confirm, however, that the representations made by Augustine and Plaintiffs’ counsel are false and misleading:

- Internally, Ridgeview representatives expressed concerned about Augustine’s statements, explaining that “there is no data to support a direct correlation to [the HotDog] product and our reduced infection rates,” “[t]here is no supportive data that we have or that the Surgeons would support the Hot Dog as the connection to reduced infection rates,” and that this had all been explained to Augustine. *See* Hulse Decl., Ex. D.
- The statement initially provided by Ridgeview to the Star Tribune – confirming that Ridgeview’s reduced infection rates were the result of its implementation of several new initiatives – was amended after Augustine complained that Ridgeview had “undermined [his] credibility.” *See id.*

- Ridgeview’s knee infection rates decreased *before* the hospital switched to the HotDog system in 2008, and its hip infection rates *actually increased* from 2006-2009 (*even after* implementation of the HotDog system). *See* Hulse Decl., Ex. E.

Notwithstanding Ridgeview’s clear and unequivocal statements to the contrary, Augustine continues to insist that the HotDog product is responsible for Ridgeview’s reduced infection rates, and that Ridgeview is “just wrong” when it says otherwise. *See* Deposition of Dr. Scott Augustine (“Augustine Dep.”) at 311:10-312:8 (Ridgeview’s statement that “there is no data to support a direct correlation to [the HotDog] and our reduced infection rates” is “just wrong” and the Ridgeview representative who made it “doesn’t know what he’s talking about”) (Hulse Decl., Ex. F). Augustine included the Ridgeview data in a paper that he submitted – and that he says was accepted – for publication, thus reflecting continued efforts to further publicize this data. *See* Augustine Dep. at 320:19-322:19 (Hulse Decl., Ex. G).

II. The Ridgeview Documents Cannot be Considered “Confidential Information” Because Their Contents Have Already Been Made Public.

In order to qualify for confidential treatment under the Protective Order and Rule 26(c), the information and documents to be protected must fall into one of the following categories: (1) trade secret information, (2) proprietary confidential information or commercially or competitively sensitive information, (3) non-public marketing information, (4) non-public detailed sales and financial data, (5) customer lists, (6) non-public technical information, or (7) other non-public information of competitive, financial, or commercial significance comparable to the foregoing categories. *See* Protective Order, Doc. No. 39 at ¶ 2; *see also* Fed. R. Civ. P. 26(c). Importantly – but not surprisingly –

information that has been disclosed or otherwise made available to the public will not be afforded confidential treatment. See Protective Order at ¶ 2 (“Information or documents that are available to the public may not be designated as Confidential Information.”). The burden is on the party seeking protection to show that the foregoing requirements are met, and “[e]ach party or non-party that designates information or items for protection under this Order must take care to limit any such designation to specific material that, in good faith, qualifies under the appropriate standards.” See *id.* at ¶¶ 4-9 (“The party asserting that the material is Confidential shall have the burden of proving that the information in question is within the scope of protection afforded by Fed. R. Civ. P. 26(c).”).

Here, the documents at issue either explicitly or implicitly contain or refer to information already disclosed to the public through the Augustine litigation guide, the YouTube videos referencing Ridgeview’s infection rates, the *Star Tribune* article, and/or other publicity generated by Augustine that includes the Ridgeview data. Thus, even if certain information could otherwise be fairly treated as confidential, the fact that the information has already been made publicly available by Augustine and Plaintiffs’ counsel necessarily precludes confidential treatment now.³ See, e.g., *In re Chrysler Motors Corp. Overnight Evaluation Program Litig.*, 860 F.2d 844 (8th Cir. 1988) (work product confidentiality waived where information was disclosed to third party, even where

³ 3M recognizes that certain of the infection data at issue may often – and appropriately – be considered confidential. In this case, however, the infection data has been publicized by Augustine and made part of his continued efforts to create false and misleading impressions about the safety of the Bair Hugger system. Because the information has already been disclosed and used publicly, however, the confidentiality that may otherwise be appropriate is not applicable here.

information was ultimately used by parties and for purposes other than what was intended at the time of initial disclosure). Ridgeview waived the confidentiality of these documents by cooperating with Augustine in using the data to promote his own agenda, and not seeking to prevent Augustine from disseminating the information publicly, in newspaper articles, the litigation guide, public presentations, and an article submitted by Augustine for publication.

The public interest also favors lifting the designation. Augustine and Plaintiffs' counsel have represented to the public that Ridgeview experienced drastically reduced infection rates when it switched from the Bair Hugger warming system to the HotDog, and have used such representations as a basis on which to recruit additional plaintiffs and encourage litigation against 3M. The Ridgeview documents prove, however, that these representations are incomplete at best, and intentionally false and misleading at worst. Regardless, neither Plaintiffs nor Augustine should be permitted to benefit – or mislead the public – by telling half-truths about Ridgeview and its experience with the Bair Hugger system. 3M, therefore, should not be prevented from using the information and documents now provided by Ridgeview to set the record straight.

CONCLUSION

For all of the foregoing reasons, 3M respectfully requests that the “confidential” designation be lifted from documents produced by Ridgeview in response to 3M's subpoena.

Dated: May 3, 2017

Respectfully submitted,

s/ Benjamin W. Hulse

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